REMARKS

Applicants respond below to the specific rejections and objections raised by the Examiner in the Final Office Action of October 2, 2003.

I. Objections and Rejections under 35 U.S.C. § 101

Claims 22-27 stand rejected under 35 U.S.C. § 101 for allegedly lacking specific and substantial asserted utility or a well established utility. The Examiner concedes on page 2 of the Office Action that the asserted utility in the present application is credible. In rejecting the claims of the present application, the Examiner has reiterated a point he raised in a previous Office Action that "the evidence in the specification provided is that the protein is related by homology to the Hep 27 protein. This relationship lacks any of the hallmarks of utility." Final Office Action, page 3, lines 5-7.

While Applicants do not deny that the PRO1800 protein disclosed in the present specification is homologous to Hep 27, Applicants once again emphasize that this relationship is not the only assertion of utility in the specification. In fact, in the Response to the Office Action filed on August 4, 2003, Applicants provided passages in the specification in which utility for the PRO1800 protein, such as use in tissue typing, and use as diagnostic and therapeutic tool, was asserted.

In the Final Office Action, the Examiner acknowledged the Applicants' arguments of the alleged utilities, but concluded that "there is no real world use for the antibody simply because the nucleic acid is overexpressed in certain cancerous cell lines." Thus, the Examiner found Applicants' arguments unpersuasive.

Applicants respectfully traverse. An Applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. § 101, "unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope." *In re Langer*, 503 F.2d 1380,1391, 183 USPQ 288, 297 (CCPA 1974). See, also *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re Irons*, 340 F.2d 974, 144 USPQ 351 (1965); *In re Sichert*, 566 F.2d 1154, 1159, 196 USPQ 209, 212-13 (CCPA 1977). Compliance with 35 U.S.C. § 101 is a question of fact. *Raytheon v. Roper*, 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983) *cert. denied*, 469 US 835 (1984). The evidentiary standard to be used throughout *ex parte* examination in setting forth a rejection is a preponderance of the totality of

the evidence under consideration. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) Thus, to overcome the presumption of truth that an assertion of utility by the applicant enjoys, the Examiner must establish that it is more likely than not that one of ordinary skill in the art would doubt the truth of the statement of utility. In other words, "Office personnel must provide evidence sufficient to show that the statement of asserted utility would be considered 'false' by a person of ordinary skill in the art." M.P.E.P. 2107.2(III)(A), February 2003, page 2100-38. Applicants respectfully submit that in rejecting the claims of the present application, the Examiner has not met this burden.

However, in order to expedite the prosecution, Applicants submit herewith as Exhibit A a Declaration by Avi Ashkenazi, Ph.D., an expert in the field of cancer biology and an inventor of a related application. This declaration was submitted in a co-owned U.S. Application Serial No. 09/903,925. As Dr. Ashkenazi explains in Paragraph 6 of the Declaration,

> even when amplification of a cancer marker gene does not result in significant over-expression of the corresponding gene product, this very absence of gene product over-expression still provides significant information for cancer diagnosis and treatment. Thus, if over-expression of the gene product does not parallel gene amplification in certain tumor types but does so in others, then parallel monitoring of gene amplification and gene product over-expression enables more accurate tumor classification and hence better determination of suitable therapy. In addition, absence of over-expression is crucial information for the practicing clinician. If a gene is amplified but the corresponding gene product is not over-expressed, the clinician accordingly will decide not to treat a patient with agents that target that gene product.

Therefore, according to Dr. Ashkenazi, medical practitioners who are interested in diagnosing cancer would not only want to know whether certain nucleic acids are overexpressed, but also whether the gene products are overexpressed as well. This information determines the course of recommended therapy.

Those of skill in the art know that one way of determining the presence of a polypeptide molecule in a sample is to run diagnostic assays using antibodies specific for that polypeptide. The antibodies of the present invention are thus useful in identifying the PRO1800 polypeptides disclosed in the specification. Because the polypeptides have a credible, substantial, and specific use in cancer diagnosis and treatment, the antibodies used in their identification will necessarily have credible, substantial, and specific utility.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the utility based rejections.

II. Rejections under 35 U.S.C. § 112, First Paragraph: Scope of Enablement

Claims 22-27 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing a subject matter which is not described in the specification in such a way as to enable one of skill in the art to make or use the invention. The Examiner states that "since there is no known use for the antibody, the antibody is not enabled for any use." The Final Office Action, page 9, lines 15-16.

Applicants respectfully traverse. As set forth above, Applicants respectfully submit that the antibodies of the present invention are useful in cancer diagnosis and treatment. Given the utility of the claimed subject matter, and the analysis under *In re Wands*, set forth in the Response of August 4, 2003, Applicants respectfully submit that the enablement rejection is now moot and respectfully request that the Examiner reconsider and withdraw the rejection.

CONCLUSION

Applicants respectfully maintain that claims are patentable and request that they be passed to issue. No fee is believed due in connection with this response. If this is incorrect, the Commissioner is hereby authorized to charge Deposit Account No. 07-0630. Applicants invite the Examiner to call the undersigned if any issues may be resolved through a telephonic conversation.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 1, 2003

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